SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)
Website: www.sinobiopharm.com
(Stock code: 1177)

VOLUNTARY ANNOUNCEMENT
PRESENTATION OF THE PHASE II CLINICAL STUDY DATA ON KRAS G12C INHIBITOR "GARSORASIB TABLET (D-1553)"

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the latest results of the Phase II clinical trial (NCT05383898) of the KRAS G12C inhibitor "garsorasib tablet (D-1553)" co-developed by the Group have been presented at the Annual Meeting 2024 of American Association for Cancer Research (AACR) for patients with KRAS G12C-mutated non-small cell lung cancer (NSCLC).

The results of this study showed that garsorasib had an objective response rate (ORR) of 50%, a disease control rate (DCR) of 89%, a median duration of response (DOR) of 12.8 months, and a median progression-free survival (PFS) of 7.6 months in patients with locally advanced or metastatic NSCLC following anti-PD-(L)1 therapy and platinum-based chemotherapy[1].

Study Method

This is an open-label, multicenter, single-arm phase II study. The primary inclusion criteria were: patients with locally advanced or metastatic NSCLC with KRAS G12C mutations, prior progressive disease or unacceptable toxicity to anti-PD-(L)1 therapy and platinum-based chemotherapy, and measurable lesions according to RECIST v1.1 criteria. The primary endpoint was ORR assessed by the Independent Review Committee (IRC) according to RECIST v1.1. The secondary endpoints included DOR, DCR, time to response (TTR), PFS, overall survival (OS), and safety.

Study Findings

As of 17 November 2023, a total of 123 patients were enrolled and treated with garsorasib 600mg twice daily (BID), in which 108 patients (88%) were male, with a median age of 64 (range: 33-80) and ECOG PS scores of 0 and 1 in 11% and 89%, respectively. As of the data cut-off date, the treatment of 82 patients had been discontinued. The median follow-up was 7.9 months (range: 0.7-16.5).

Efficacy data: 1 patient had a complete response, 60 patients had a partial response, and 48 patients were stable. The IRC-confirmed ORR was 50% (61/123, 95% CI, 41-59) and the DCR was 89% (109/123, 95% CI, 82-94). The median DOR was 12.8 months (95% CI, 6.2-NE). The median PFS was 7.6 months (95% CI, 5.6-9.7), and the median OS has not yet been reached.

Safety data: The most reported (≥25%) treatment-related adverse events (TRAEs) (any grade) were elevated aspartate aminotransferase, alanine aminotransferase, and γ-glutamyl transferase, anemia, elevated blood bilirubin, and elevated serum alkaline phosphatase. No new safety signals were identified in the study, and most of the adverse events were well controlled. At the same time, the TRAEs that led to permanent discontinuation did not occur.

Conclusions of the Study

The results of the study showed that garsorasib showed a high tumor response rate and a longer duration of response in NSCLC patients harboring the KRAS G12C mutation, and it was also well tolerated and controllable in terms of safety[1]。For this patient population with unmet medical needs, garsorasib is expected to be a promising treatment option.

Regarding Garsorasib

KRAS mutations commonly exist in various high lethality cancers, of which KRAS G12C is a specific KRAS mutation, representing approximately 44% of all KRAS mutations. KRAS G12C mutation is more common in lung, colorectal, pancreatic and bile duct cancers. According to Frost & Sullivan, from 2016 to 2020, the number of new patients in the PRC suffering from major KRAS G12C mutation cancers increased from 38,000 to 43,000, and it is estimated that such number will reach 58,000 by 2030, with huge market potential.

D-1553 is the first domestic independently developed KRAS G12C inhibitor to enter clinical trial stage, and is also the first domestic KRAS G12C inhibitor which was granted Breakthrough Therapy designation by the Center for Drug Evaluation (CDE) of the National Medical Products Administration. In December 2023, the new drug application for D-1553 for the treatment of locally advanced or metastatic NSCLC with disease progression following or intolerant to prior first-line systemic therapy and with confirmed KRAS G12C mutation has been accepted, and has been included in the priority review and approval procedures in January 2024. In addition, international multi-center clinical studies of D-1553 as a monotherapy and as drug combination in the first-line treatment of NSCLC and other solid tumors such as colorectal cancer are ongoing, and some of the study results have been published on influential international academic conference platforms, all of which have demonstrated good safety and anti-tumor activity.

In August 2023, the Group entered into a license and cooperation agreement with InventisBio and was granted an exclusive license to develop, register, manufacture and commercialize the latter's KRAS G12C-targeted drug D-1553 product in Mainland China. The Group will accelerate the development of new indications in the future, further explore and maximize the clinical application value of D-1553 and benefit more patients.

Source:

[1] Open-label, single-arm, multicenter, phase 2 trial of garsorasib in KRAS G12C-mutated non-small-cell lung cancer. 2024 AACR

By order of the Board
Sino Biopharmaceutical Limited
Tse, Theresa Y Y
Chairwoman

Hong Kong, 11 April 2024

As at the date of this announcement, the Board of the Company comprises seven executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin, Mr. Tian Zhoushan and Ms. Li Mingqin and five independent non-executive directors, namely Mr. Lu Zhengfei, Mr. Li Dakui, Ms. Lu Hong, Mr. Zhang Lu Fu and Dr. Li Kwok Tung Donald.